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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,746	11/16/2000	Christoph Kessler	1803-277-999	0382

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ROCHE MOLECULAR SYSTEMS INC
PATENT LAW DEPARTMENT
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EXAMINER

SIRZELECKA, TERESA I

ARTICLE PATENT NUMBER

1637

DATE MAILED 09/30/2002

21

Please find below and or attached an Office communication concerning this application or proceeding

Office Action Summary

Application No.

09/530,746

Applicant(s)

KESSLER ET AL.

Examiner

Teresa E Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group 1, claim(s) 1-15, drawn to a method of detection nucleic acids, comprising amplifying the nucleic acid with primers A and C', contacting the amplification product with a probe of sequence D which binds to a sequence B located between sequences A and C, and detecting the formation of a hybrid between the amplification product and the probe.
- II. Group 2, claim(s) 16-19, drawn to a method for detection of nucleic acids comprising amplifying the nucleic acid with two primers, where one of the primers is not specific for the group of organisms to which the detected organism belongs, contacting the amplification product of less than 100 nucleotides with a probe which binds to the amplification product and detecting the hybrid between the amplification product and the probe.
- III. Group 3, claim(s) 20-21, drawn to a method for simultaneous production of amplicates using primers selected such that the amplification products do not do not differ by more than 20% in length and do not exceed 100 nucleotides.
- IV. Group 4, claim(s) 22-23, drawn to a method for detection of HCV using two primers and one probe whose sequences are derived from the HGBV sequence.
- V. Group 5, claim(s) 24-25, drawn to a method of detection nucleic acids, comprising amplifying the nucleic acid with primers, A and C', selected such that the amplification products do not do not differ by more than 20% in length and do not exceed 100 nucleotides.

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contacting the amplification products with a probe of sequence D which binds to a sequence B located between sequences A and C, and detecting the formation of a hybrid between the amplification products and the probe.

2. The inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups 1-5 are drawn to methods of nucleic acid detection or amplification using different conditions (primers and probes). The special technical feature of Group 1 is detection based on amplification with two primers A and C' and detection with a probe D; the special technical feature of Group II is amplification with two primers one of which is not specific and producing an amplification product of less than 100 nucleotides; the special technical feature of Group III is amplification using primers which result in the final products differing by no more than 20% in length and shorter than 100 nucleotides; the special technical feature of Group 4 is detection of HCV using primers and probes derived from the HGBV sequence, and the special technical feature of Group 5 is detection based on amplification with two primers, A and C', selected such that the amplification products do not do not differ by more than 20% in length and do not exceed 100 nucleotides, and detection with a probe D.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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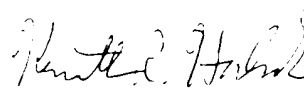
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
September 25, 2002

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KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

9/26/02